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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,213	04/12/2001	Harukazu Fukami	001560-390	3646

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EXAMINER

HABTE, KAHSAY

ART UNIT

PAPER NUMBER

1624

DATE MAILED: 04/24/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/763,213	FUKAMI ET AL.
	Examiner Kahsay Habte, Ph. D.	Art Unit 1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 08 April 2003.

2a) This action is FINAL.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 1-6 and 13-25 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-3 and 13-25 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.

4) Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.

5) Notice of Informal Patent Application (PTO-152)

6) Other: \_\_\_\_\_

### **DETAILED ACTION**

1. Claims 1-6 and 13-25 are pending.

#### **Request for Continued Examination**

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 4/8/03 has been entered.

#### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Fukami et al. (US Pat. No. 5,814,631). The cited reference on column 52 (example 148) teaches the synthesis of 3-(4-aminobenzenesulfonyl)-7-chloro-2,4(1H,3H)-quinazolinedione. The said compound is exactly the same as applicants when applicant's formula (1) has the following substituents:

X = chloro at 7 position; A = phenyl; R1 = amino at 4-position; and R2 = R3 = hydrogen.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fukami et al. (US Pat. No. 5,814,631). The cited reference on column 52 (example 148) teaches the synthesis of 3-(4-aminobenzenesulfonyl)-7-chloro-2,4(1H,3H)-quinazolinedione. The said compound is exactly the same as applicants except that it is excluded by the proviso. Applicants claim 2-aminobenzenesulfonyl and 3-aminobenzenesulfonyl, but excluded the 4-aminobenzenesulfonyl. First of all it is a position isomer (see below for further discussion). Secondly, in the reference the substituents on the A ring are floating (see formula I). Thirdly, the cited reference also teaches substituents on the 2 or 3 positions (see example 127 on column 48).

It is well established that position isomers are *prima facie* structurally obvious even in the absence of a teaching to modify. The isomer is expected to be separable by the same method and to have generally the same properties. This expectation is then deemed the motivation for preparing the position isomers. This circumstance has

arisen many times. See: *Ex parte Englehardt*, 208 USPQ 343, 349; *In re Mehta*, 146 USPQ 284, 287; *In re Surrey*, 138 USPQ 67; *Ex Parte Ullerot*, 103 USPQ 185; *In re Norris*, 84 USPQ 459; *Ex Parte Naito*, 168 USPQ 437, 439; *Ex parte Allais*, 152 USPQ 66; *In re Wilder*, 166 USPQ 545, 548; *Ex parte Henkel*, 130 USPQ 474; *Ex parte Biel*, 124 USPQ 109; *In re Petrzilka*, 165 USPQ 327; *In re Crownse*, 150 USPQ 554; *In re Fouche*, 169 USPQ 431; *Ex parte Ruddy*, 121 USPQ 427; *In re Wiechert*, 152 USPQ 249, *In re Shetty*, 195 USPQ 753.

For example, "Position isomerism has been used as a tool to obtain new and useful drugs" (Englehardt) and "Position isomerism is a fact of close structural similarity" (Mehta, emphasis in the original). See also MPEP 2144.09, second paragraph.

Since the only difference between the compound of the cited reference and applicants is a position isomer, it would have been obvious to a person of ordinary skill in the art at the time of the invention was made to change the positions of the substituents on the phenyl to avoid prior art.

#### ***Response to arguments***

5. A declaration was submitted on 4/8/03, but the declaration is not signed, thus it is invalid. Even if it were signed, the declaration would not have overcome the obviousness rejection of claims 1-6 in Paper No.11 (item 4) for the following reason:

Applicants have not compared Fukami's compound 148 with its isomers. The comparison should be done between the compound of example 148 i.e. 3-(4-aminobenzenesulfonyl)-7-chloro-2,4(1H,3H)-quinazolinedione and its position isomer

i.e. 3-(2-aminobenzenesulfonyl)-7-chloro-2,4(1H,3H)-quinazolinedione or 3-(3-aminobenzenesulfonyl)-7-chloro-2,4(1H,3H)-quinazolinedione. Applicants' compounds 13, 17, and 18 are acids. The solubilities may be higher because of the acid. For example, Fukami's compound has  $-\text{NH}_2$  while applicant's Example 13 has aminocarbonyl propionic acid. Thus, one cannot compare the solubility of an acid with an amine for comparison.

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 25 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. There has been added a proviso in claim 25, but there is no descriptive support in the specification for the said proviso. The proviso lacks description. Even a negative limitation requires description, *Ex Parte Grasselli*, 231 USPQ 393. Specifically, there is no description in the specification that links the definitions of  $\text{R}^1$  = amino,  $\text{R}^2 = \text{R}^3$  = hydrogen to that of choices of 2-aminobenzenesulfonyl or 3-aminobenzenesulfonyl. Indeed, even these two groups lack specific mention.

***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 and 13-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention:

a. Claim 1 and claims dependent thereon are rejected because the phrase "R2 and R3....(b) an unsubstituted or substituted C1 to C4 lower alkyl group" is indefinite. Substituted by what? What are covered and what are not? Like wise in claim 25 the phrase "R2 and R3....(b) an unsubstituted or substituted C1 to C4 lower alkyl group" is also indefinite.

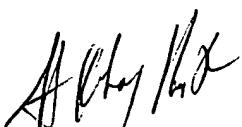
b. In claims 14-17 (Paper No. 10), the phrase "prevention or" should be removed from the claims. Applicants deleted the method of prevention to overcome a 112 first paragraph enablement rejection, but forgot to remove said phrase from the claim.

***Conclusion***

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kahsay Habte, Ph. D. whose telephone number is (703) 308-4717. The examiner can normally be reached on M-F (9.00AM- 5:30PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 703-308-4716. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Kahsay Habte, Ph. D.  
Examiner  
Art Unit 1624



Mark L. Berch  
Primary Examiner  
Art Unit 1624

KH  
April 21, 2003